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TECHNICAL MANUAL

METRON ACCUSONIC PLUS ULTRASOUND THERAPY UNIT

MODEL AP 100

Prepared by
Metron Medical Australia P/L
Version 1.6 March 2002

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EC DECLARATION OF CONFORMITY

Metron Medical Australia Pty Ltd
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Carrum Downs, Australia, 3201

declares that the medical devices described hereafter:

Metron Accusonic Plus Ultrasound Therapy Unit

Model: AP 100

is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC

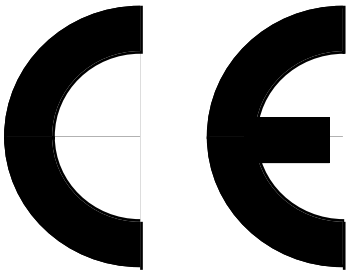
is subject to the procedure set out in Annex II of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS Yarsley International Certification Services Ltd, Portland Road, East Grimstead, W Sussex RH19 4ET.

Melbourne, 23 August 1999

R. H. Hopkins

Technical Director

On Behalf Of
Metron Medical Australia Pty Ltd



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The Metron Accusonic Plus Ultrasound Therapy Unit bears the above marking in accordance with the requirements of Council Directive 93/42/EEC.

Should you as the user of this technical manual wish to make any comment about the product or this manual our Authorised Representative within the European Union may be contacted as follows:

Metron Medical
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1. SPECIFICATIONS

MAINS SUPPLY REQUIREMENTS:

Voltage	110 - 120 Volts AC or 220 - 240 Volts AC
Frequency	50/60 Hz
Power	75VA Maximum

FUSES:

Primary external	2 of 1A 5 X 20 mm DA205
Internal Fuse	1 of 4A 5x20mm DA205

POWER SUPPLY:

Integrated switchmode power supply complying with IEC 601-1: 1988 and amendments.

Secondary Voltages	24 Volts DC @ 2.7A

ULTRASOUND OUTPUT - 1 MHz:

Frequency	1.1 MHz +/- 10%
Output Intensity, Continuous Mode	3.0 Watts/cm^2 +/- 20% Maximum
Power/Intensity Display	Accurate to +/- 20% of reading for outputs in excess of 0.2 Watts/cm^2.
Effective Radiating Area	5.0 square cms +/- 20%.

ULTRASOUND OUTPUT - 3 MHz:

Frequency	3.3 MHz +/- 10%
Output power in continuous mode	3.0 Watts/cm^2 +/- 10% maximum (Equivalent to 2.4 watts absolute for the 1cm head) 1.6 Watts/cm^2 +/- 10% maximum (Equivalent to 8.0 watts absolute for the 2.5 cm head)

Effective Radiating Area	Nominally 0.8 square cms +/- 20% (1 cm head) Nominally 5.0 square cms +/- 20% (2.5 cm head)
Power/Intensity Display	Accurate to +/- 10% of reading for outputs in excess of 1 Watt.

ULTRASOUND MODULATION:

Modulation Modes	Continuous Pulsed
Pulsed Modulation	
Pulse Frequency	100 Hz +/- 2%
Pulse Width	1.0, 2.0, 5.0 milliseconds +/- 2%
Pulse Duty Cycle	1:9 (10%), 1:4 (20%), 1:1 (50%) respectively

BEAM NON-UNIFORMITY RATIO: 5:1 +/- 20%

TREATMENT TIMER:

Maximum Treatment Time	30 minutes +/- 2%
At Time Expiration	Time display zeros and a 3 second audible alarm sounds.

CONTACT CONTROL:

Function	To detect poor acoustic coupling between the ultrasonic treatment applicator and the patient.
On detection of contact loss	The LED indicator on the selected applicator handle turns red and, after a 2 second delay, the treatment timer is halted. The ultrasonic output is reduced to 0.2 Watts/cm^2.
On detection of contact	The treatment timer is restarted and the ultrasonic output power is restored to the selected value. The LED indicator on the applicator handle turns green.
Purpose/Rationale	Ensures the patient receives the required ultrasound dose and prevents damage to the ultrasonic treatment applicator by heat generated in the transducer when it is operated unloaded at high power levels.

ELECTRICAL SAFETY:

Designed and manufactured to comply with the following Australian and International standards:

AS 3100 - 1985	Definitions and general requirements for electrical materials and equipment.
AS 3200.1 - 1990	Approval and test specification - Medical electrical equipment, Part 1 General requirements for safety.
AS 3200.2.5 - 1992	Approval and test specification - Medical electrical equipment, Part 2: Particular requirements for safety - Ultrasonic therapy equipment.
IEC 601-1 - 1988	Medical electrical equipment, Part 1: General requirements.
IEC 601-2-5 - 1984	Medical electrical equipment, Part 2: Particular requirements for the safety of ultrasonic therapy equipment.

Applied part	Treatment applicator/s
Applied part classification	BF
Chassis classification	1

DIMENSIONS:

Width	170 mm
Height	120 mm
Depth	280 mm

WEIGHT:

Packed	3 Kg
Unpacked	2.5 Kg

ENVIRONMENTAL CONDITIONS:

Operating:	Temperature Range	10 - 40 ^{o}C
	Relative Humidity	30% - 90%
Transport & Storage:	Temperature Range	0 - 70 ^{o}C
	Relative Humidity	10% - 100%

2. INTRODUCTION

This manual presents all the relevant technical information for the Metron Accusonic Plus Ultrasound Therapy Unit. This information is provided as a service to medical, paramedical, engineering and technical personnel. This information is intended for the fair purposes of evaluation, maintenance and repair of the Accusonic. It is provided as commercial-in-confidence material to the distributor or equipment purchaser and shall not be made available to any other organisation or person without the specific written permission of Metron Medical Australia Pty Ltd. Refer to the Metron Accusonic Plus Operator Manual for operator information.

All functions of the schematic diagram are described. Necessary preventative maintenance calibration adjustments are described in detail. Recommended electrical safety inspection procedures are discussed.

While every attempt has been made to ensure that this manual is accurate and complete, no responsibility is taken for any errors or omissions. Specifications and component types are subject to change without notice.

If you, as a user of this manual, have any relevant comments or questions, your communication with us would be welcomed. You may contact us by mail or fax as detailed below:

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The Accusonic Plus generates continuous and pulsed wave ultrasound. The ultrasonic transducer in the ultrasonic treatment applicator is driven by an approximately sinusoidal voltage derived from a micro-computer generated 1 MHz or 3 MHz signal and tuned power amplifier. The amplitude of the transducer drive voltage determines the ultrasonic power output. This power output is controlled by the power supply voltage to the tuned power amplifier. The ultrasonic power output is proportional to the square of the power supply voltage. The necessary parameters to control the supply voltage to appropriate levels are stored in the connector of the treatment applicators.

The power supply voltage is generated by a programmable power supply which employs a monolithic switch - mode voltage regulator. This supply is controlled by a pulse width modulated signal generated by the microcontroller.

This microcontroller also performs a number of other operations crucial to the device. It processes all the keyboard functions and drives all the 7 segment displays. It also acts as the treatment timer and drives the audible alarm.

The degree of acoustic coupling between the ultrasonic treatment applicator and the patient is monitored by the contact sense circuit and the microcontroller. At detection of contact loss the indicator on the selected applicator turns RED, the treatment timer is halted and after 2 seconds of contact loss the ultrasonic output power is reduced from that selected to 0.2 Watts/cm^2. At detection of contact the treatment timer resumes and the ultrasonic output power is restored to the selected value.

This ensures the patient receives the ultrasound dose selected and prevents damage to the ultrasonic treatment applicator by the heat that would be generated in the ultrasonic transducer if it was operated unloaded at high power levels.

3. SCHEMATIC DIAGRAM DESCRIPTION

3.1 PRINTED CIRCUIT BOARD (see Schematic, page 11)

3.1.1 Main Power Supply.

The DC voltage from the switchmode power supply is applied to the electronics through the diode bridge BR1. The bridge provides a level of protection against wiring errors. The 24 volt DC supply supplies power to switching regulators IC11, & IC12 and the Piezo speaker.

Switching regulator IC11 supplies +5 volt rail at 1A. Switching regulator IC12 is the variable voltage supply. This supply is used to power the output amplifier from 0 to +25 volts DC at 3A. The power supplies output voltage is controlled by the microcontroller via filtering components R2, C29 & R5.

3.1.2 Oscillator, Output Stage & Contact Sense Control.

IC7 & IC8 form a PLL up convertor to generate the 1MHz signal for the output stage. An input frequency of 61Hz is applied to pin 14 of IC7 from the microcontroller and is multiplied by the PLL circuit 16385 times to a value of 1MHz or 3 MHz on pin 4 of IC9. IC10B is used to gate this signal for pulsed mode. This signal is than buffered by IC9 to drive Q1 the output stage.

Alignment of the treatment applicators is controlled by the microcontroller and the tune point of the applicators is stored in the eeprom located in the connector of the treatment applicator.

L5 monitors supply current level in the output stage. Comparing this value with preset values stored in eeprom, signals an in-contact or contact loss. If an contact loss condition is encountered, the microcontroller reduces the output power to 1W total (0.2 Watts/cm^2) and pauses the timer. When contact is reestablished the timer is restarted & power level is restored to that selected. IC10A, IC10B & IC10C drive the bi-colour LEDs in the treatment applicators for contact status.

Two output connectors are provided, J1 and J2, and the selection of one particular connector is controlled by the “Applicator” key on the front panel and the microprocessor. Relays RL1 and RL2 provide the necessary switching.

3.1.3 Microcontroller

IC13 resets the microcontroller IC1 on power up. The control program is stored in memory IC3 and IC2 provides the address latching for IC3. IC4 provides the external memory enable control.

The microcontroller monitors the keys and contact status and controls the drive signal frequency, the seven segment displays, the piezo speaker drive and the treatment applicators power output.

3.1.4 Displays & Drivers

The seven segment displays, LED 11 and LED 12, and the individual LEDs, LED1 through LED8, are driven by display drivers chips IC5 and IC6. These 35 segment drivers and controlled by serial information sent from the microprocessor to their CK and DATA pins. The display intensity is determined by R11 and R17. capacitors C25 and C28 provide filtering and voltage stabilisation.

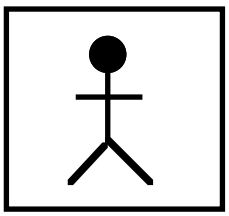
3.2 ULTRASONIC TREATMENT APPLICATOR/S

(see Schematic page 12)

The ultrasonic treatment applicator consists of a plastic and aluminium assembly with the ultrasonic transducer bonded in position. The contact loss indicator LED is driven by the LED signal from the contact sense circuit on the main PCB. The LED has a capacitor connected in parallel with it to prevent the transducer drive RF from turning it on.

The piezoelectric resonator which generates the ultrasound energy is permanently bonded to the cap of the applicator. It can be replaced by simply unscrewing the cup and resonator and attaching a new cup and resonator.

The connector of the treatment applicator contains a small printed circuit board which houses IC1 and filter capacitor C1. IC1 is an EEPROM which is programmed during the calibration sequence, see page 8, and stores the critical information relating to optimum tune frequency and supply voltage levels for each output setting necessary to maintain calibration.



This symbol indicates that the applied parts (treatment applicators) of this equipment are rated as Type “BF”. This means that the patient applied parts are suitable for placement on the external surface of the patient without creating a safety hazard.

4. PREVENTATIVE MAINTENANCE / QUALITY ASSURANCE

4.1 Calibration and Adjustment

4.1.1 Equipment Required

The following equipment is a minimum requirement for the calibration of the Metron Accusonic Plus.

Ultrasound Power Meter: Ohmic Instruments UPM-30
Bio-Tek Instruments UW-II
UMA Inc UMT-2A or equivalent

4.1.2 Calibration Procedure

Connect the applicator to be calibrated to either input on the Accusonic Plus.

NOTE: It is recommended that treatment applicators only be attached and removed from the unit when the power is turned OFF.

Calibration mode can only be accessed by pressing the “Timer Down” button and “Mode” button at the same time and then turning the power ON. This will place the unit into alignment mode (Timer will display an "F"). For the 3 MHz 5 sqcm head select “LF” using the “Timer Down” button.

The first step is to align the frequency of the selected applicator. Remove any water, gel etc from face of the applicator and place in free air (face of applicator not in contact with anything). Select the frequency, using the “Timer Up” button, press the “Mode” button and wait until the power display counts from 0 to 99.

When completed the timer display will show a "P" indicating the next step, the alignment of the applicator’s output power and contact sense control, is ready to be undertaken. Place the applicator in the power meter.

Press the “Mode” button and adjust the applicator output power, as displayed, using the “Power Up/Down” buttons to match the power output displayed on the ultrasound power meter. The first calibration point takes place with a mid point output power setting, 8 watts (1 MHz 5sqcm), 5 watts (3 MHz 5 sqcm) and 1.3 watts (3 MHz 0.75 sqcm) . When this adjustment is completed press the “Mode” button to move on to the next power level for adjustment.

Repeat the above procedure for the other two power settings, 2 and 15 watts (1MHz 5 sqcm), 0.3 and 2.4 watts (3MHz 0.75 sqcm) or 2 and 10 watts (3MHz 5 sqcm) then press the “Mode” button again. This will initiate the contact sense alignment mode which automatically scans each power level for each pulse mode to determine the contact parameters. The treatment applicator should not be removed from the ultrasound power meter until this procedure has finished.

The calibration procedure for that particular treatment applicator is now completed. If another applicator needs calibration repeat the above procedure.

At the completion of the calibration procedure it is required that the mains power be turned OFF and then turned ON again to return the Accusonic Plus to the normal operation mode.

WARNING: If the mains power is removed or turned OFF prior to the completion of the calibration of an applicator the whole procedure will need to be repeated.

4.2 Electrical Safety Inspection

A program of regular electrical safety inspections for this equipment is recommended. The type and frequency of testing may be obtained from locally published standards. In Australia, the relevant standards are:

AS 3511 - 1988	Acceptance testing and in-service testing - Electromedical equipment
AS 2500 - 1986	Guide to the safe use of electricity in patient care.

A hospital biomedical engineering department or third party service organisation nominated by the manufacturer or distributor would be capable of performing the necessary testing and providing suitable documentation.

Programmed electrical safety inspections are recommended to confirm continued operator and patient safety. Other mandatory statutory requirements for electrical safety inspections may also apply.

4.3 Disassembling/Assembling the Unit

If required disassembly and assembly of the unit should be undertaken with extreme care to avoid damage to the surfaces of the enclosure. Whenever the unit has to be turned upside down, place it on a soft surface or thick cloth.

Disassembly of the unit is as follows:

- Place the unit upside down on a soft cloth. Remove the four pozi-head screws around the perimeter of the base. Two are located close to the front edge of the base and two are located close to the rear edge of the base.

- Turn the unit up the right way and carefully lift the top away from the base. The two halves can now be separated sufficiently to allow access to all components.

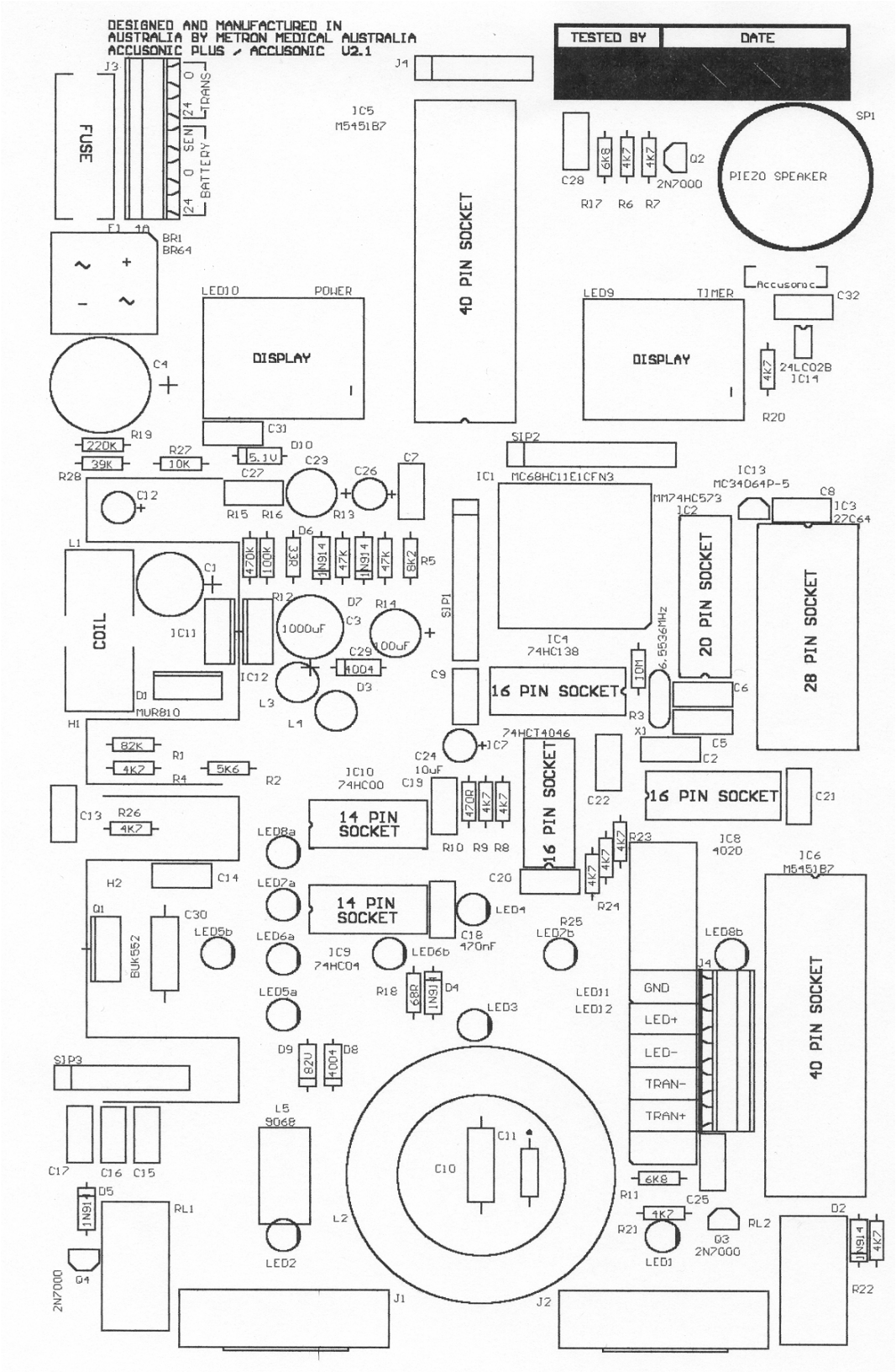
Assembly is a reverse procedure of the above with several precautions. They are:

- Observe that any connectors, cables or wires that were removed are correctly reinstated and are not fouled or crushed.

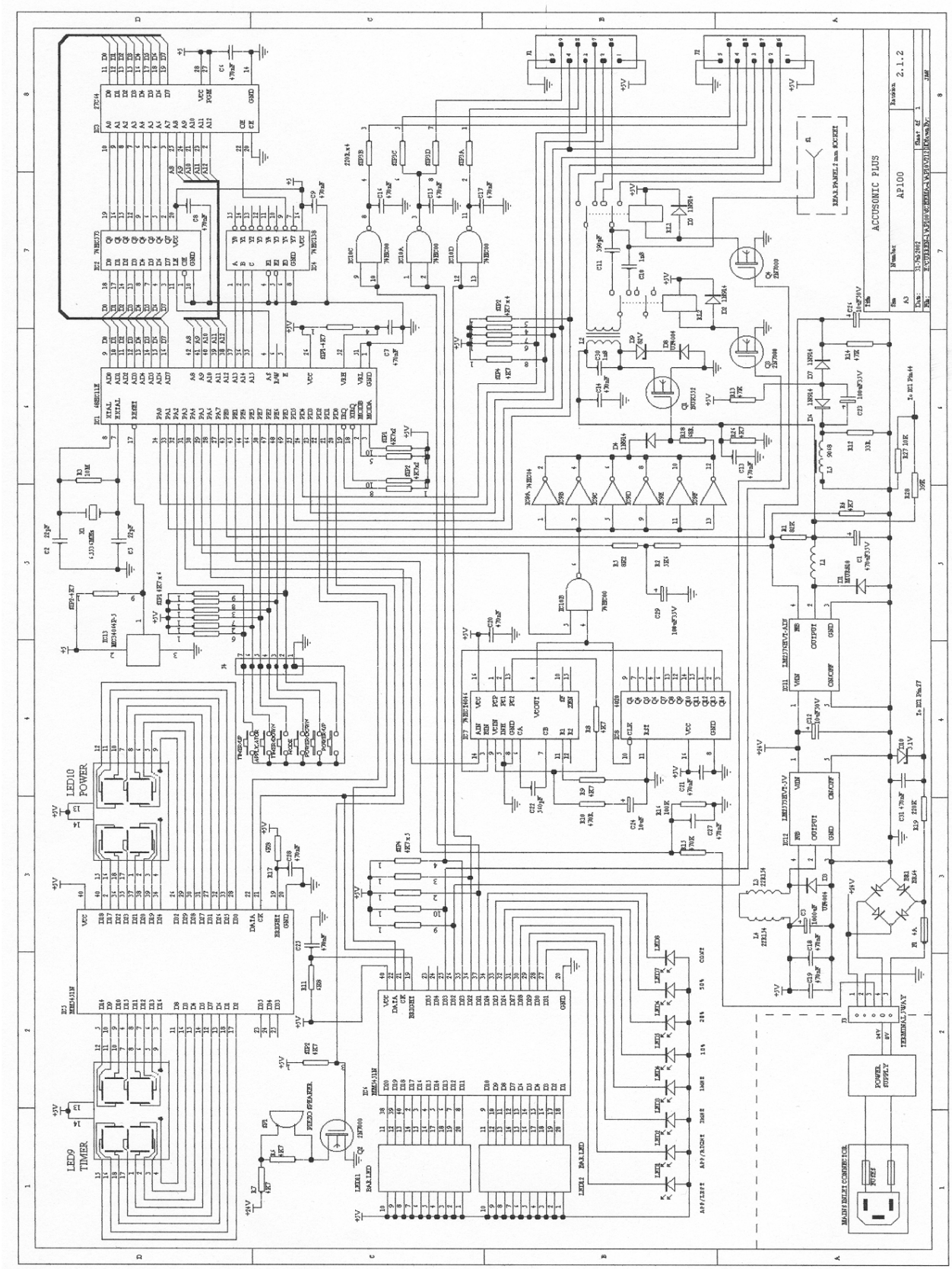
- Avoid over tightening the screws which secure the top to the base.

5. SCHEMATIC DIAGRAMS

5.1 Main Circuit Board Layout



5.2 Schematic Diagram - Main Printed Circuit Board



5.3 Schematic Diagram - Treatment Head Printed Circuit Board